

Application Number 10/731,869
Amendment dated November 28, 2005
Responsive to Office Action mailed July 28, 2005

REMARKS

This amendment is responsive to the Office Action dated July 28, 2005. Applicant has amended claims 1, 16, 23, 33, 34 and 39, and cancelled claim 32. Claims 1-31 and 33-57 are pending.

Claim Rejections Under 35 U.S.C. § 102

In the Office Action, the Examiner rejected claims 1, 2, 11-23, 32-42 and 51-55 under 35 U.S.C. § 102(b) as being anticipated by US 5,645,586 to Meltzer (Meltzer). Applicant respectfully traverses these rejections to the extent that such rejections may be considered applicable to the amended claims. Meltzer fails to disclose each and every feature of the claimed invention, as required by 35 U.S.C. § 102(b), and provides no teaching that would have suggested the desirability of modification to include such features.

Claims 1, 2 and 11-22

For example, Meltzer fails to teach or suggest an implantable medical device including first and second housings that are coupled, and wherein the coupling of first and second housings allows the housings to have a plurality of degrees of freedom of movement relative to each other, as required by Applicant's independent claim 1 as amended. Instead, contrary to this requirement, Meltzer describes a device wherein housing segments are coupled by a hinge, which allows only a single, rotational degree of freedom of movement of the segments with respect to one another.¹ Nothing within Meltzer would have even suggested coupling the housing segments to provide multiple degrees of freedom of movement to one of ordinary skill in the art.

Similarly, dependent claim 17 requires an interconnect member that couples the housings and allows a plurality of degrees of freedom of movement of the housing relative to each other. The Examiner argued that the hinges described by Meltzer are interconnect members between housings. However, as discussed above, these hinges provide only a single degree of freedom of movement.

¹ E.g., FIGS. 3 and 4; col. 3, ln. 65 – col. 4, ln. 48. Notably, FIG. 5 and the accompanying text of Meltzer describe an embodiment without multiple housing segments. All embodiments with housing segments include a hinge.

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As another example, claim 18 requires that each of the first and second housings is substantially cylindrical. Directly contrary to this requirement, Meltzer discloses housing segments 23-25 that are hexahedral or "cube-like."² Meltzer does not disclose or suggest any other shape for the housing segments, much less cylindrical housing segments. In fact, because Meltzer teaches hexahedral housing segments that are maintained in close proximity and connected along their adjacent sides by a hinge, one of ordinary skill would have consciously avoided modification of the Meltzer housing segments to be substantially cylindrical. Such a modification of the Meltzer housing segments would have deprived the Meltzer device of the closely proximate adjacent sides desired for the described housing segment connections.

In support of the rejection of claim 18, the Examiner cited col. 4, ll. 1-15 of Meltzer. The cited portion of Meltzer teaches that the hexahedral housing segments include complementary cylindrical terminating portions that combine to form a hinge between the segments. However, this teaching of a cylindrical portion attached to an otherwise hexahedral housing is irrelevant to the requirement in claim 18 of housings that are substantially cylindrical.

Further, the Examiner either overlooked, or misunderstood the requirements of claim 21. Claim 21 requires that the overmold is shaped for implantation on a cranium of a patient. Meltzer provides no teaching regarding either the shape of the biocompatible polymer described at col. 4, ll. 44-48, or implantation of the device described therein on the cranium. Accordingly, Meltzer fails to teach or suggest this requirement of claim 21.

Meltzer fails to disclose each and every limitation set forth in claims 1, 2 and 11-22. For at least this reason, the Examiner has failed to establish a *prima facie* case for anticipation of Applicant's claims 1, 2 and 11-22 under 35 U.S.C. § 102(b). Withdrawal of these rejections is requested.

Claims 23 and 32-38

Similar to dependent claim 17, independent claim 23 requires an interconnect member that flexibly couples first and second housings, wherein the interconnect member is flexible in a

² Meltzer, FIG. 2.

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plurality of directions and allows the first and second modules to have a plurality of degrees of freedom of movement relative to each other. Dependent claim 33 further requires that the interconnect member allows the modules to have at least three degrees of freedom of movement relative to each other. The Examiner argued that the hinges disclosed by Meltzer are interconnect members within the meaning of claims 23 and 33. However, as discussed above, the hinges provide only a single, rotational degree of freedom of movement.

Further, as amended, claim 34 requires that the interconnect member defines a lumen between the housings. The various hinges described by Meltzer do not define a lumen between the described housing segments. Meltzer makes no mention of a lumen between the housing segments.

Also, like claim 18, claim 35 requires that the housings are substantially cylindrical. For the reasons discussed above with reference to claim 18, Meltzer fails to teach or suggest this requirement of claim 35.

Meltzer fails to disclose each and every limitation set forth in claims 23 and 32-38. For at least this reason, the Examiner has failed to establish a prima facie case for anticipation of Applicant's claims 23 and 32-38 under 35 U.S.C. § 102(b). Withdrawal of these rejections is requested.

Claims 39-41

Similar to dependent claim 17, independent claim 39 requires an interconnect member that flexibly couples first and second housings, wherein the interconnect member is flexible in a plurality of directions and allows the first and second modules to have a plurality of degrees of freedom of movement relative to each other. Dependent claim 40 further requires that the interconnect member allows the modules to have at least three degrees of freedom of movement relative to each other. The Examiner argued that the hinges disclosed by Meltzer are interconnect members within the meaning of claims 39 and 40. However, as discussed above, the hinges provide only a single, rotational degree of freedom of movement.

For at least this reason, the Office Action has failed to establish a prima facie case for anticipation of Applicant's claims 39-41 under 35 U.S.C. § 102(b). Withdrawal of these rejections is requested.

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Claims 42 and 51-55

Independent claim 42 requires a first module comprising control electronics and a therapy delivery circuit housed within a first housing, and a second module comprising a power source within a second housing. Meltzer fails to teach or suggest these requirements of independent claim 42. In particular, Meltzer provides no teaching with respect to where in the three disclosed housing segments the various components of the disclosed implantable medical device are located. Meltzer certainly does not even suggest that control electronics and a therapy delivery circuit are located together within one of the three housing segments, while a power source is located within another of the three housing segments.

Further, the arrangement of components within housings recited in claim 42 is not inherent in the Meltzer. Inherency requires that one of ordinary skill in the art would have necessarily understood the recited arrangement to be part of the Meltzer disclosure, to the exclusion of other possible arrangements.³ The mere possibility that one skilled in the art might interpret a general disclosure as including undisclosed features is insufficient to show inherency.⁴ Meltzer is silent as to the arrangement of components within the disclosed housing segments, and one of ordinary skill in the art would have understood that numerous arrangements of components within the Meltzer housing segments are possible. Accordingly, one of ordinary skill would not have understood the claimed arrangement to necessarily be within the Meltzer disclosure, as required for inherency. None of the other references cited by the Examiner suggest such the arrangement of components within housings recited by claim 42.

As another examples, like claims 17, 23 and 39, claim 51 requires an interconnect member that is flexible in a plurality of directions and allows the first and second modules to have a plurality of degrees of freedom of movement relative to each other. Further, like claim 21, claim 53 requires that the overmold is shaped for implantation on a cranium of a patient. For the reasons discussed above, Meltzer fails to disclose or suggest these requirements of claims 51 and 53.

³ See *Finnigan Corp. v. ITC*, 51 USPQ2d 1001, 1009 (Fed. Cir. 1999).

⁴ See *id.*

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Meltzer fails to disclose each and every limitation set forth in claims 42 and 51-55. For at least this reason, the Examiner has failed to establish a prima facie case for anticipation of Applicant's claims 42 and 51-55 under 35 U.S.C. § 102(b). Withdrawal of these rejections is requested.

Claim Rejection Under 35 U.S.C. § 103

In the Office Action, the Examiner rejected claims 3-10, 24-31, 43-50, 56 and 57 under 35 U.S.C. § 103(a) as being unpatentable over Meltzer in view of US 6,176,879 to Reischl et al. (Reischl), and rejected claim 55 under 35 U.S.C. § 103(a) as being unpatentable over Meltzer in view of US 6,567,703 to Thompson et al. (Thompson). Applicant respectfully traverses these rejections to the extent that such rejections may be considered applicable to the claims as amended. The applied references fail to disclose or suggest the inventions defined by Applicant's claims, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed invention.

Claims 56 and 57

For example, independent claim 56 requires control electronics and a rechargeable power source within a first housing, and a recharge coil within a second housing. Meltzer does not even suggest a rechargeable power source and a recharge coil. Further, as discussed above, Meltzer does not teach or suggest any particular arrangement of components within the disclosed housing segments. Moreover, Reischl discusses only two device configurations: control electronics, a power source and a recharge coil within a single common housing 11 (FIG. 2); or an unhoused recharge coil contained in a silastic jacket attached to a housing (Background). Accordingly, nothing within Reischl would suggest modification of Meltzer to include control electronics and a power source within a first housing, and a recharge coil within a second housing.

Additionally, neither Meltzer nor Reischl teaches or suggests a flexible tether member between first and second housings, as required by independent claim 56, or that the flexible tether member comprises a helix, as required by dependent claim 57. The hinges disclosed by Meltzer are not flexible tethers, and Meltzer certainly does not suggest that they comprise a helix. The Examiner appears to have overlooked these requirements of claims 56 and 57. Applicant

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respectfully requests that the Examiner address each and every requirement of Applicant's claims, including claims 56 and 57, when issuing any subsequent Office Action.

For at least these reasons, the Examiner has failed to establish a prima facie case for non-patentability of Applicant's claims 56 and 57 under 35 U.S.C. § 103(a). Withdrawal of this rejection is requested.

Claims 3-10, 24-31, 43-50 and 55

Initially, Applicant notes that neither Reischl nor Thompson provides any teaching that would overcome the deficiencies of Meltzer with respect to the requirements of Applicant's independent claims discussed above. For at least this reason, the Office Action has failed to establish a prima facie case for non-patentability of Applicant's claims 3-10, 24-31, 43-50 and 55 under 35 U.S.C. § 103(a), and the rejections of each of these claims should be withdrawn. Moreover, the applied references, either alone or in combination, fail to teach or suggest a number of the requirements recited in these claims.

For example, as discussed above with reference to claim 57, the applied references fail to disclose or suggest a flexible tether member between housings that comprises a helix, as required by each of dependent claims 10, 31 and 50.

Further, none of the applied references even suggests a recharge coil that substantially encircles first and second modules, as required by claims 5, 26 and 45. As acknowledged by the Examiner, Meltzer fails to teach or suggest a recharge coil. Reischl discusses a recharge coil, but does not teach or suggest that the recharge coil substantially encircles other modules of a medical device, as required by claims 5, 26 and 45.

Instead, as clearly shown in FIG. 2, Reischl teaches locating a recharge coil 26 in a separate, ceramic housing portion 12, away from the other device components.⁵ Because Reischl teaches that locating a recharge coil 26 in this manner is an advantage of their invention, Reischl would have taught away from any modification of Meltzer to include a recharge coil that substantially encircles other modules, as required by claims 5, 26 and 45. In other words, even

⁵ See also Reischl, col. 3, ll. 35-63.

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when combined, the cited references fail to teach or suggest a recharge coil that substantially encircles other modules, as required by claims 5, 26 and 45.

Also, it is again unclear whether the Examiner has addressed this requirement of claims 5, 26 and 45. Applicant respectfully requests that the Examiner address each and every requirement of Applicant's claims, including claims 5, 26 and 45, when issuing any subsequent Office Action.

For at least these reasons, the Examiner has failed to establish a prima facie case for non-patentability of Applicant's claims 3-10, 24-31, 43-50 and 55 under 35 U.S.C. § 103(a). Withdrawal of this rejection is requested.

Rejection for Obviousness-type Double Patenting:

The Examiner provisionally rejected claims 1-57 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-23 of copending Application No. 10/731,638. Applicant notes the provisional status of this rejection. Accordingly, Applicant will address this issue if and when the rejection is formally applied.

CONCLUSION

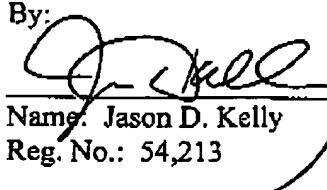
All claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims. Please charge any additional fees or credit any overpayment to deposit account number 50-1778. The Examiner is invited to telephone the below-signed attorney to discuss this application.

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